

Subpart C—Drugs Eligible for Purchase under 340B

10.20 Drugs eligible for purchase Under 340B.

10.21 Exclusion of orphan drugs for certain covered entities.

AUTHORITY: Sec. 340B of the Public Health Service Act (42 U.S.C. 256b), as amended; Sec. 215 of the Public Health Service Act (42 U.S.C. 216), as amended; Sec. 526 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 360bb); Sec. 701(a) of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 371(a)); Sec. 1927 of the Social Security Act, as amended (42 U.S.C. 1396r-8).

SOURCE: 78 FR 44027, July 23, 2013, unless otherwise noted.

Subpart A—General Provisions

§ 10.1 Purpose.

This part implements section 340B of the Public Health Service Act (PHSA) “Limitation on Prices of Drugs Purchased by Covered Entities.”

§ 10.2 Summary of 340B Drug Pricing Program.

Section 340B of the PHSA instructs the Secretary of Health and Human Services to enter into agreements with manufacturers of covered drugs under which the amount required to be paid to these manufacturers by certain statutorily-defined entities does not exceed the average manufacturer price for the drug under title XIX of the Social Security Act (SSA) reduced by a rebate percentage which is calculated as indicated in 340B(a)(1) and 340B(a)(2)(A). Manufacturers participating in the 340B Drug Pricing Program (340B Program) are required to provide these discounts on all covered outpatient drugs sold to participating 340B covered entities.

§ 10.3 Definitions.

Ceiling price means the maximum statutory price established under section 340B(a)(1) of the PHSA.

Covered entity means an entity that meets the requirements under section 340B(a)(5) of the PHSA and is listed in section 340B(a)(4) of the PHSA.

Covered outpatient drug has the meaning set forth in section 1927(k) of the SSA.

Group purchasing organization (GPO) is an entity that contracts with purchasers, such as hospitals, nursing homes, and home health agencies, to aggregate purchasing volume and negotiate final prices with manufacturers, distributors, and other vendors.

Manufacturer has the same meaning as set forth in section 1927(k)(5) of the SSA.

Orphan drug means a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Participating drug manufacturer means a manufacturer that has entered into a Pharmaceutical Pricing Agreement with the Secretary.

Pharmaceutical Pricing Agreement (PPA) means an agreement described in section 340B(a)(1) of the PHSA.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Section 340B means section 340B of the PHSA.

Subpart B—Eligibility To Purchase 340B Drugs

§ 10.10 Entities eligible to participate in the 340B Drug Pricing Program.

Only organizations meeting the definition of a covered entity and listed on the 340B database are eligible to purchase covered outpatient drugs under the 340B Program. A covered entity remains responsible for complying with all other 340B requirements and applicable Federal, state, and local laws.

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The definition of a covered outpatient drug has the meaning given to such term in section 1927(k)(2) of the SSA except as provided in § 10.21 of this part.